EXHIBIT 17

[redacted]

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,	)	
Plaintiff,	)	
v.	)	
SAREPTA THERAPEUTICS, INC.,	)	
Defendant.	)	**C.A. No. 21-1015-GBW**
SAREPTA THERAPEUTICS, INC.,	)	
Defendant/Counter-Plaintiff,	)	
v.	)	
NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC.	)	
Plaintiff and Counter-Defendants.	)	

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Wilmington, Delaware
Wednesday, May 3, 2023
Markman Transcript

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BEFORE: HONORABLE GREGORY B. WILLIAMS
UNITED STATES DISTRICT COURT JUDGE

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Michele L. Rolfe, RPR, CRR

case, here the parties dispute numerous factual issues, including even the level of the skilled artisan. There are multiple competing expert declarations that have been submitted, but there's been no depositions that have been taken. Fact discovery is on-going and expert discovery has not yet begun.

Now, Sarepta's motions are supported by the declaration of Dr. Cy Stein, and very briefly, he's cofounded The Oligonucleotide Therapeutic Society in 2004, and was awarded its lifetime achievement award in 2022. He has decades of experience in the field and he's published over 140 peer-reviewed articles.

So turning to term one, which the parties have called the antisense oligonucleotide phrase. Sarepta's position that this phrase is not indefinite and that no construction is needed. It's Nippon Shinyaku's position that it is indefinite.

The parties have offered competing constructions of the term to the extent a construction is needed. Sarepta's construction requires that the antisense oligonucleotide be 100 percent complementary to its target. Nippon Shinyaku's alternative construction does not require 100 percent complementarity for the antisense oligonucleotide, but only for a portion of it. So only part of the oligonucleotide needs to be complimentary.

So looking at the claim term, "An antisense oligonucleotide of the 20 to 31 bases comprising a base sequence that is 100 percent complementary to consecutive bases of a target region of exon 53 of the human dystrophin pre-mRNA."

These terms operate together to define the invention, as I'll discuss in a minute. And there are multiple cases that say that claim terms should not be interpreted in a vacuum and that the context of the surrounding words of the claims must be considered.

For example, in the ACTV case, there was a broader claim term, and one party advocated for just interpreting one word within the broader term. But the Court determined that the words operated and provided context for one another and themselves must be construed so the entire phrase needed to be construed.

So let's see how this works, and I'm going to walk through this. So, first of all, the claim recites "an antisense oligonucleotide." That's shown here on slide 10, the blue hexagons represent the backbone portion of the antisense oligonucleotide. And the purple circles with the Bs in them represent the base portion of the oligonucleotide.

Now, the claim recites that it is 20 to 31 bases, which means that there are between 20 and 31 of these

units in the oligonucleotide.

Shown here is an oligonucleotide with 21 bases as an example.

The claim recites that there is a base sequence. That is the sequence of bases of the oligonucleotide, that's what a base sequence is. So if the oligonucleotide has 21 bases, as shown here, then the base sequence is 21 nucleotides. And if the oligonucleotide has 31 bases, then the base sequence would be 31 bases. That's what the oligonucleotide sequence is.

The claim term also recites "exon 53 of the human dystrophin pre-mRNA," that's shown here. This is a part of the pre-mRNA that encodes for the dystrophin protein.

The claim recites "to consecutive bases of a target region of exon 53," that's shown here with the yellow circles with the Bs in them, which are consecutive segment of the human dystrophin pre-mRNA.

And the claim recites that there is "100 percent complementarity between the bases of the oligonucleotide and the bases of the exon 53 human dystrophin pre-mRNA," and that's shown with this -- dotted green lines indicating that they are able to bind to one another through Watson and Crick pairing, like a double helix, to use an analogy, it's base pairing that compliments sequences to another.

So Sarepta's expert, Dr. Stein, explained this, that Sarepta's construction conveys this. You have an antisense oligonucleotide that has 20 to 31 bases, which collectively form a sequence, the base sequence, that is 100 percent complementary to a segment of the pre-mRNA, the target region, transcribed from exon 53 of the human dystrophin again.

Now, Sarepta's construction accounts for all of the claim terms in term one. And this is responsive to an argument from Nippon Shinyaku. First of all, Nippon Shinyaku argues that Sarepta's construction reads out the term comprising, and respectfully we disagree with that.

The construction allows for other elements present in the claimed oligonucleotide, so it's not just the base sequence, there can be other things, like, for example, the backbone or caps that occur at one end of the oligonucleotide.

Nippon Shinyaku also argues that Sarepta's construction doesn't account for the terms "consecutive bases of a target region." And, again, we disagree. Sarepta's construction requires the base sequence of the antisense oligonucleotide to be 100 percent complementary to a segment of the pre-mRNA i.e., bases arranged in a consecutive manner. So there's nothing being written out of the construction. Sarepta's construction accounts for all

deprotecting agent. But, again, nothing in the claims or the specifications suggest that such indirect reactions are allowed, either under the plain claim language or the sole embodiment disclosed in the specification.

NS's counsel argue that somehow it is wrong that Sarepta's construction read out this method B. But respectfully, there's nothing that the come -- that NS's claim cannot cover method B under Sarepta's constructions. The claim says what it says, and the claims as written should be construed, as the Federal Circuit explained in the *Chef America*.

And for those reasons, Sarepta's construction should be adopted because it is based on the plain claim language and is also consistent with the intrinsic evidence, including the sole embodiment in the specification, and that's how the skilled artisan would have understood, as explained by Dr. Pentelute.

THE COURT: All right. I understand your argument.

MR. MILLER: Just a few very quick points, Your Honor. First, my opposing counsel mentioned the fact that the claims have lettered steps and numbered compounds, and argued that those letters and numbers imported a -- implied a step order.

Your Honor, respectively, those letters and

numbers are used for organizational purposes, so that in later dependent steps, instead of reciting the entire step, the dependent claim -- I'm sorry, in dependent claims, instead of reciting an entire step from the independent claim, the independent claim can simply identify step E as the one being further modified, or other steps like that.

And the same reason those numbered compounds are provided numbers, so you can use a shorthand instead of repeating the structure of each numbered compound every single time it's used, you can just recite to the earlier numbered structure.

I'd also like to pull up slide 21 from my opposing counsel's presentation. And I think this generally shows the improper way that -- that Sarepta has construed these claims. Sarepta is -- if you look at the claims themselves, they say "reacting said Compound 3. And reacting said Compound 4."

Instead of looking at that claim language, Sarepta is importing the underlined limitations from the specification, from an embodiment in the specification that Compound 3 must be produced in step B or produced in step C into the claims themselves.

And we already know that importing limitations from the specification, from an embodiment in the specification, even if it is the only embodiment in the

specification, that's improper. And for those reasons, NS's proposed construction should be adopted, Your Honor.

THE COURT: All right.

MR. MILLER: Thank you.

THE COURT: Thank you.

All right. The Court wants to thank counsel on both sides for your presentations today. The Court will take these matters under advisement and issue a *Markman* ruling as soon as it can. We've been trying to get them out within 60 days, so we will do our best in keep that up.

So with that, that's all I had on the agenda for the day for these parties, so with that we are adjourned.

(Whereupon, the following proceeding concluded at 1:13 p.m.)

I hereby certify the foregoing is a true and accurate transcript from my stenographic notes in the proceeding.

/s/ Michele L. Rolfe, RPR, CRR

U.S. District Court